COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss		SUPERIOR COURT
COMMONWEALTH OF MASSACHUSETTS,	)	
	)	
v.	)	
	)	
PURDUE PHARMA L.P., PURDUE PHARMA INC., RICHARD SACKLER, THERESA SACKLER, KATHE SACKLER, JONATHAN SACKLER, MORTIMER D.A. SACKLER, BEVERLY SACKLER, DAVID SACKLER, ILENE SACKLER LEFCOURT, PETER BOER, PAULO COSTA, CECIL PICKETT, RALPH SNYDERMAN, JUDITH LEWENT, CRAIG LANDAU, JOHN STEWART, MARK TIMNEY, and RUSSELL J. GASDIA.	)	CIVIL ACTION NO. 1884-CV-01808 (BLS2)

PURDUE'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS AMENDED COMPLAINT

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Purdue Pharma L.P. and Purdue Pharma Inc. (collectively, "Purdue") respectfully submit this memorandum of law in support of their motion to dismiss the Commonwealth of Massachusetts's ("the Commonwealth") Amended Complaint pursuant to Mass. R. Civ. P. 12(b)(6).[1]

PRELIMINARY STATEMENT

The Commonwealth's lengthy and hyperbole-filled Amended Complaint seeks to vilify Purdue and its employees and directors,[2] claiming falsely that "Purdue Pharma created the [opioid] epidemic" and that the individual defendants "made the choices that caused much of the opioid epidemic." Am. Compl. ¶¶ 2, 170. The Commonwealth's Amended Complaint is replete with sensational and inflammatory allegations, but utterly neglects to meet its burden to allege legally viable claims. This Court should carefully examine the legal theories propounded, look beyond the rhetoric to apply longstanding Massachusetts law requiring that causation be established in cases involving lawfully available FDA-approved medicines, and dismiss the Commonwealth's Amended Complaint as oversimplified scapegoating based on a distorted account of the facts unsupported by applicable law.

To be sure, there is an opioid abuse crisis in the Commonwealth, but the responsibility for this crisis cannot, as a matter of law, be tied to one company that manufactures a tiny fraction of the prescription opioids in the Commonwealth. In seeking to do so, the Commonwealth attempts to displace the medical judgments of its own public health experts and those at FDA and

[1] Unless otherwise noted, emphasis in quotations is added, and internal citations, quotation marks, and alterations are omitted.

[2] The Commonwealth also brings the same claims against Purdue's former directors (the "Director Defendants"), its former and current CEOs (the "CEO Defendants") and a former employee, Russell J. Gasdia. These claims will be addressed in separate motions to dismiss to be filed on behalf of these individuals.

undermines the efforts of those tasked with understanding the causes of the crisis and working collaboratively on solutions.

As the Commonwealth's Department of Public Health's findings show, Purdue neither created nor caused the opioid epidemic in Massachusetts. In reports analyzing the crisis, experts at the Massachusetts Department of Public Health found "[n]o single substance or health care practice is solely responsible for the current opioid crisis. Rather, it's a complex issue with a number of contributing factors."[3] *See* Ex. F at 7. The Department of Health further found that the

[3] Purdue attaches the following exhibits to the accompanying Affidavit of Timothy C. Blank in connection with its motion to dismiss: (1) The 2007 Consent Judgment referenced in ¶¶ 193, 859 of the Amended Complaint (Ex. A), (2) the current FDA-approved labeling for OxyContin® (Ex. B), (3) a 2013 FDA denial of a "Citizen's Petition" submitted by Physicians for Responsible Opioid Prescribing ("PROP") (Ex. C), (4) the Commonwealth's 2016 Chapter 55 report entitled, "An Assessment of Opioid Related Deaths (2013-2014)," available at https://www.mass.gov/media/971976/download (Ex. D); (5) the Commonwealth's 2017 Chapter 55 report entitled, "An Assessment of Fatal and Nonfatal Opioid Overdoses in Massachusetts (2011-2015)," available at https://www.mass.gov/media/1573931/download (Ex. E); (6) Home page of the Commonwealth's Chapter 55 website, available at https://chapter55.digital.mass.gov/ (Ex. F); (7) a publication entitled "Data Brief: Opioid-Related Overdose Deaths among Massachusetts Residents (Feb. 2019)," available at https://www.mass.gov/lists/current-opioid-statistics#updated-data---q4-2018---as-of-february-2019- (Ex. G); (8) The Massachusetts OxyContin and Other Drug Abuse Commission Final Report, available at https://archives.lib.state.ma.us/bitstream/ handle/2452/265674/ ocm70914663.pdf?sequence=1&isAllowed=y (Ex. H); (9) a presentation by Dr. Douglas C. Throckmorton entitled "FDA Perspective on Abuse-Deterrent Opioid Development," available at https://www.fda.gov/ downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM545923.pdf (Ex. I); (10) a presentation by Dr. Douglas C. Throckmorton entitled "FDA's Actions To Address The Opioid Epidemic," available at https://www.fda.gov/downloads/AboutFDA/CentersOffices/ OfficeofMedicalProductsandTobacco/CDER/UCM601178.pdf (Ex. J); (11) an FDA publication entitled "Abuse-Deterrent Opioid Analgesics," available at https://www.fda.gov/Drugs/DrugSafety/ PostmarketDrugSafetyInformationforPatientsand Providers/ucm600788.htm (Ex. K); (12) an FDA publication entitled "FDA Analysis of Long-Term Trends in Prescription Opioid Analgesic Products: Quantity, Sales, and Price Trends," available at https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/ UCM598899.pdf (Ex. L); (13) the "Recommendations of the OxyContin and Heroin Commission of the Commonwealth of Massachusetts" dated November 2009, available at https://archives.lib.state.ma.us/ bitstream/handle/2452/46748/ ocn466141823.pdf?sequence=1 (Ex. M); (14) the 2015 "Recommendations of the Governor's Opioid Working Group," available at https://www.mass.gov/files/2017-08/ recommendations-of-the-governors-opioid-working-group.pdf (Ex. N); (15) Table 8 of the MassHealth (the Commonwealth's Medicaid Provider) Covered Drug List, available at https://masshealthdruglist.ehs.state.ma.us/MHDL/pubtheradetail.do?id=8 (Ex. O); (16) a 2014 report from the Massachusetts Department of Public Health entitled "Findings of the Opioid Task Force and Department of Public Health Recommendations on Priorities for Investments in Prevention, Intervention, Treatment and Recovery" available at https://www.mass.gov/files/documents/2016/07/tp/report-of-the-opioid-task-force-6-10-14.pdf (Ex. P); and (17) the 2012 "Citizen's Petition" submitted by Physicians for Responsible Opioid

epidemic of overdose deaths in Massachusetts is primarily attributable to abuse of heroin and illicit fentanyl, and not lawful prescription opioid pain medicines. Consistent with that finding, the Commonwealth's most recently released data on opioid-related overdose deaths shows that in 2018, 89% of those tested had a positive screen result for fentanyl (primarily illicitly produced and sold, not prescription fentanyl) and heroin was also present in 34% of the cases. *See* Ex. G. Given its own data, it is unsurprising that the Department of Health acknowledged in 2016 that "[w]hile prescription drug use can result in addiction and may increase the long-term risk of death, illegal drugs appear more likely to be the direct cause of death," are "driving the increases in overdose" and are the "proximal causes of overdose." *See* Ex. D at 9, 27.

Given the Department of Health's findings that illicit rather than lawful opioids cause the great majority of opioid overdose-related deaths in the Commonwealth, Purdue's medications (let alone Purdue's alleged conduct) cannot, as a matter of law, be the cause of the opioid abuse crisis. Purdue's OxyContin constitutes an exceedingly small percent of the prescription opioids prescribed in the country (currently less than 2% and never more than 4%) and, thus, a tiny fraction of a fraction of all opioids (licit and illicit) used and abused in the Commonwealth and elsewhere.

When stripped of its sensational language, the Commonwealth's allegations primarily amount to an accusation that Purdue improperly marketed its medications for long-term therapy at high doses—the treatment doctors usually choose for their sickest patients. But FDA has repeatedly approved Purdue's medicines for that purpose. Indeed, in a 2013 response to a citizen

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Prescribing ("PROP"), available at https://www.regulations.gov/document?D=FDA-2012-P-0818-0001 (Ex. Q). Exhibits B through Q are all publicly available, either on federal government websites (Exs. B, C, I, J, K, L, and Q) or on the Commonwealth's own websites (Exs. D, E, F, G, H, M, N, O, and P). The attached documents were either specifically referenced in the Commonwealth's Amended Complaint or are matters of public record; they may therefore be judicially noticed by this Court. *Reliance Ins. Co. v. City of Boston*, 71 Mass. App. Ct. 550, 555 (2008). Judicial notice of such documents is proper on a motion to dismiss. *Jarosz v. Palmer*, 436 Mass. 526, 530 (2002).

petition seeking to limit opioids to a certain duration and daily dose, FDA not only rejected those requests, *see* Ex. C, but declined to impose warnings about increased risks due to longer therapy and higher doses—warnings the Commonwealth now asserts Purdue failed to provide to Massachusetts doctors. The Commonwealth's efforts to substitute its judgment over FDA's and hold Purdue liable for not providing the warnings that FDA, in its expert view of the science, declined to impose cannot stand.

Recognizing the weakness of its legal theories, the Commonwealth has resorted to the creation of a sensationalist and distorted narrative that ignores facts and mischaracterizes numerous e-mails and business documents. As set forth below, the Amended Complaint contains many inaccuracies about both Purdue and the individual defendants, including claims about the abuse-deterrent formulation of OxyContin, claims that Purdue improperly promoted higher doses of its medications, claims that Purdue improperly tried to influence hospitals and medical organizations in the Commonwealth, and many other misleading statements. But no matter how incendiary the Amended Complaint makes Purdue's conduct sound, the Commonwealth has not cured the deficiencies with its legal claims. When this Court looks beyond the Commonwealth's inflammatory language and examines the legal sufficiency of the Commonwealth's causes of action under the Massachusetts Consumer Protection Act and for public nuisance, it will be apparent that both have significant legal defects that require dismissal.

PROCEDURAL HISTORY

The Commonwealth filed its original 77 page complaint in June 2018 against Purdue and the individual officers and directors. Defendants responded in September 2018 with motions to dismiss. Rather than respond to the Defendants' motions, the Commonwealth amended its complaint; presumably in an effort to address the deficiencies in its claims. In December 2018,

the Commonwealth filed a 274 page Amended Complaint that, through selective quotation and mischaracterization from Purdue's confidential business documents, crafts an inaccurate narrative of Purdue's actions, and those of its individual employees and directors.[4] The Amended Complaint has succeeded in drawing widespread media coverage of the Commonwealth's lawsuit. But the additional 200 plus pages in the Amended Complaint have done nothing to address the legal insufficiencies in the Commonwealth's consumer protection and public nuisance claims against Purdue.

BACKGROUND FACTS

A. Chronic Pain Is A Serious Public Health Problem, Which Purdue's FDA-Approved Opioids Help To Address

Purdue's opioid medications OxyContin®, Butrans®, and Hysingla® are extended release, long-acting ("ER/LA") opioid analgesics that relieve chronic pain that is often severe and debilitating. FDA has specifically approved each of these medications as safe and effective for the long-term treatment of chronic pain. FDA's approval of OxyContin was based on six controlled clinical trials – two more than was then required by prevailing industry standards. These clinical trials involved over 700 patients, with only two patients demonstrating any evidence of abuse. Ex. B. at § 6.1.

FDA has repeatedly acknowledged that opioid medications like Purdue's OxyContin® serve an important public health role: "When prescribed and used properly, opioids can effectively manage pain and alleviate suffering—clearly a public health priority. Chronic pain is a serious and growing public health problem: it 'affects millions of Americans; contributes greatly to

[4] As will be more fully explained in the motions to dismiss to be filed on behalf of the individual defendants, the Amended Complaint attempts to confer jurisdiction over these defendants by misdescribing documents in an effort to establish suit-related contacts where none exist.

national rates of morbidity, mortality, and disability; and is rising in prevalence.'" Ex. C, at 2. Despite the Commonwealth's current allegation that the safety and efficacy of OxyContin for long-term use has not been established, the Commonwealth has, in the past, repeatedly reaffirmed the need to "ensure access to pain medication for individuals with chronic pain" (Ex. N at 2), noting that "prescription opioid pain medications serve an important and legitimate role in the treatment of pain" (Ex. P at 11). Likewise, FDA has approved and continues to approve the long-term use of ER/LA opioids to treat chronic pain. Indeed, for over 23 years, and with more than 30 labeling changes, OxyContin is FDA approved for "long-term" use to this day. FDA-approved labeling of OxyContin has always included warnings on the risk of abuse and misuse. In 2001, FDA modified the OxyContin labeling and required Purdue to disclose in its FDA-approved labeling: "Opioids also have grave risks, the most well-known of which include addiction, overdose, and even death." Ex. C at 2. In 2001, the label also added a black box warning that specifically warned that OxyContin carried a risk of abuse and misuse. And the current black box warning contains the following language:

> **WARNING: ADDICTION, ABUSE AND MISUSE . . .**
>
> - **OXYCONTIN exposes users to risks of addiction, abuse and misuse, which can lead to overdose and death. Assess each patient's risk before prescribing and monitor regularly for these behaviors and conditions.**

Ex. B, at 1. (*emphasis in original*).

Purdue continues to comply with FDA requirements, listing all of these risks in the current OxyContin package insert. The Commonwealth does not allege to the contrary. Notwithstanding these warnings and the strict regulatory scheme under which Purdue marketed and sold these medications, the Commonwealth asserts that Purdue "deceived doctors and patients" in order to get more people on its opioids "at higher doses, for longer periods." Am. Compl. ¶ 18. But Purdue

was (and is) permitted to market its opioid medications consistent with FDA-approved labeling, including for long-term treatment of chronic pain. That Purdue employed sales representatives to visit doctors and provide them with information about Purdue's medications is not only legal, but also standard industry practice.

Furthermore, FDA has already addressed many of the same criticisms leveled by the Commonwealth, and concluded that no modification to OxyContin's labeling was necessary. In 2012, an independent group, Physicians for Responsible Opioid Prescribing, filed a Citizen's Petition ("PROP Petition") with FDA, requesting that three major changes be made to opioid analgesics' labeling: (1) strike "moderate" from the indication for non-cancer pain; (2) add a maximum daily dose for non-cancer pain; and (3) add a maximum duration of 90 days for continuous use for non-cancer pain. Ex. Q at 2. The PROP Petition argued that ER/LA opioids' then-current indication for "moderate to severe pain, when a continuous, around the clock analgesic is needed for an extended period of time," was overly broad and implied that ER/LA opioids are safe and effective for long-term use. Ex. Q at 1. PROP further claimed that the long-term safety and effectiveness of managing chronic non-cancer pain with opioids has not been established and that chronic opioid therapy is associated with an increased risk of overdose death, emergency room visits and fractures in the elderly. Ex. Q at 2. Finally, based on a sample of medical, pharmacy, and claims records, PROP contended that two-thirds of patients who used opioids on a daily basis for 90 days were still taking them five years later. Ex. Q at 2. In other words, the PROP Petition presented FDA with the same assertions that the Commonwealth makes in its Amended Complaint.

For fourteen months, FDA carefully reviewed the petition, evaluated the studies PROP cited, researched the other available scientific literature, convened a two-day workshop, held a

two-day public hearing, and considered the opinions of experts, medical associations, patients, and over 2,500 public comments. In September 2013, FDA responded to the petition. Concluding that available data and studies failed to show a causal relationship between higher doses/longer durations and higher risks to patients, FDA denied PROP's request to limit the indication for chronic opioid therapy to any particular duration or daily dose. Ex. C at 12-16. FDA also did not require revision of the labeling to include additional risk information about a supposed "lack of evidence to support long-term use." *Id.* at 12, 14-16.[5] Nor did FDA direct Purdue to cease marketing the medications for long-term use. *Id.* at 14-15 ("[The] FDA has determined that limiting the duration of use for opioid therapy to 90 days is not supportable."). FDA also refused to recommend a "maximum . . . duration of use." *Id*. at 11. While FDA did enhance some safety warnings related to abuse and addiction in response to the PROP Petition, FDA expressly declined to add a warning that high doses and long durations of opioid treatment create greater risks to patients. Thus, when presented with the very same concerns about the enhanced risks of using opioids in high doses and long durations the Commonwealth now raises, FDA chose neither to impose those limits on opioid use nor to add warnings about those risks. In the face of all of the science that has subsequently developed, FDA has continued to find the product labeling appropriate.[6]

[5] Indeed, the FDA recognized that "numerous uncontrolled studies . . . have evaluated patients on opioids for as long as a year" and "although some patients drop out of the studies over this period of time, many remain on opioid therapy, which may suggest that they continue to experience benefits that would warrant the risks of opioid use." Ex. C at 10, n.40.

[6] The FDA-approved labeling also discusses the concept of pseudoaddiction, distinguishing between "drug seeking behavior" and the fact that "[p]reoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control." Ex. B. § 9.2; *compare* Am. Compl. ¶ 77 (alleging that "Purdue peddled the false notion that patients suffered from pseudoaddiction").

Similarly, many of the Commonwealth's allegations regarding Purdue's marketing have already been addressed as a result of the 2007 Consent Judgment. Ex. A. In 2007, Purdue entered into a Consent Judgment with 27 State Attorneys General, including Massachusetts, in order to resolve claims regarding the marketing of OxyContin. While the Commonwealth discusses the Consent Judgment in its Amended Complaint, *see, e.g.*, Am. Compl. ¶ 193, 194, 195, it ignores two critical facts. First, under the Consent Judgment, Purdue was obligated to provide annual reports to the Commonwealth for three years "containing basic statistics on Purdue's Abuse and Diversion Program including, but not limited to, statistics on the number of reports, the number of investigations, and a summary of the results, including the number of 'Do Not Call' determinations." Ex. A at ¶ 24(e). The Consent Judgment also provided that "upon written request, the Attorney General may obtain state-specific information as described in subsection (e)" and that "Purdue agrees to accept service of a civil investigative demand . . . requesting the names of any specific Health Care Professionals described in subsection (e)." *Id.* at ¶ 24(f). The Commonwealth does not claim that Purdue violated these provisions of the Consent Judgment or that Purdue failed to provide any required information to the Commonwealth.[7] Second, Purdue also agreed to enter into a five-year Corporate Integrity Agreement ("CIA") with the Office of the Inspector General of the U.S. Department of Health & Human Services ("OIG"). The key focus areas of the CIA included sales, marketing, advertising, promotion, and dissemination of information and materials related to the selling of certain Purdue products. During the term of this five-year agreement, Purdue submitted annual reports to a designated OIG monitor and engaged an Independent Review Organization that evaluated specified elements of Purdue's compliance

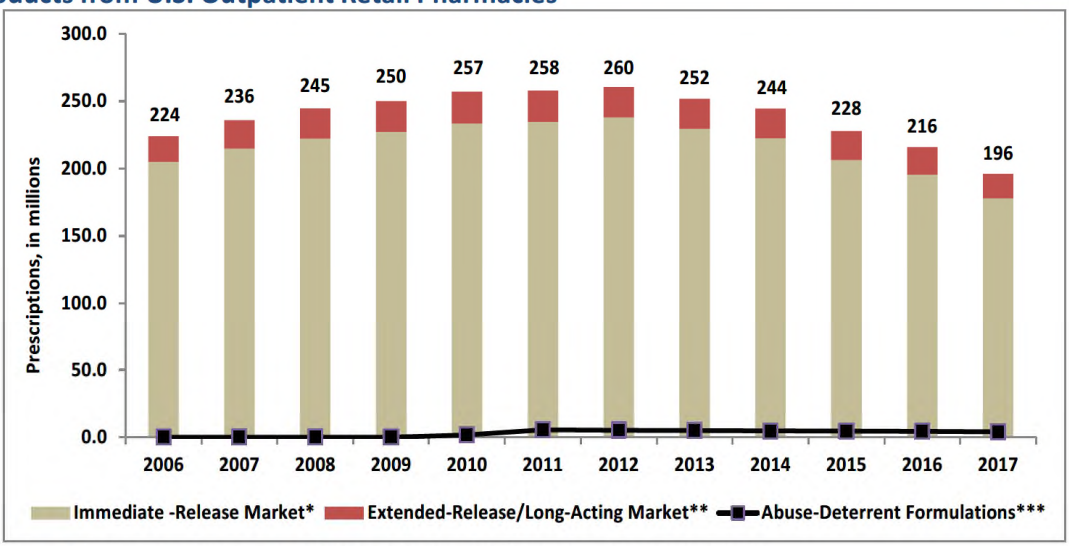
[7] The Commonwealth did not request the name of any Health Care Professional pursuant to the Consent Judgment. Years later, the Commonwealth did serve a Civil Investigative Demand on March 25, 2015 requesting the names of certain physicians and Purdue provided the requested information.

program on a periodic basis to assess compliance with the terms of the CIA. Thus, one of the most glaring omissions in the Amended Complaint is its failure to recognize that Purdue successfully satisfied its obligations under the CIA and the agreement was ended in 2013.

B. Purdue's OxyContin Accounts for a Small Percentage of Available Opioids

The vast majority (approximately 90%) of opioid prescriptions written in this country are for immediate release medications, not ER/LA medications. Of the small percent of prescriptions written for ER/LA products, only a very small portion are for abuse-deterrent products like Purdue's OxyContin®. *See* Ex. I at 25. OxyContin® is one of just 8 products for which FDA currently approves labeling describing abuse-deterrent properties. *See* Ex. K at 2-3. These abuse-deterrent products have, according to FDA, "found very low uptake" and thus make up a very small fraction of the overall prescription opioid market. *See* Ex. L at 7. This is graphically demonstrated in a March 2018 FDA presentation showing the small percentage of ER/LA products and the tiny portion of abuse deterrent formulations:

Nationally Estimated Number of Prescriptions Dispensed for Opioid Analgesics Products from U.S. Outpatient Retail Pharmacies



Source: IQVIA, National Prescription Audit (NPA) and static data 2006-2011. January 2006-December 2017.
Static data extracted March 2017 and 2012-2017 data extracted February 2018.
*Immediate-Release formulations include oral solids, oral liquids, rectal, nasal, and transmucosal
**Extended-Release/Long-Acting formulations include oral solids and transdermal patches
***Abuse-deterrent formulation opioid products include Arymo ER, Embeda ER, Hysingla ER, Morphabond ER, Xtampza ER, OxyContin ER Reformulated (Approval in April 2010)
Note: Include opioid analgesics only, excluding injectable formulations as well as opioid-containing cough-cold products and opioid-containing medication-assisted treatment (MAT) products

www.fda.gov 9

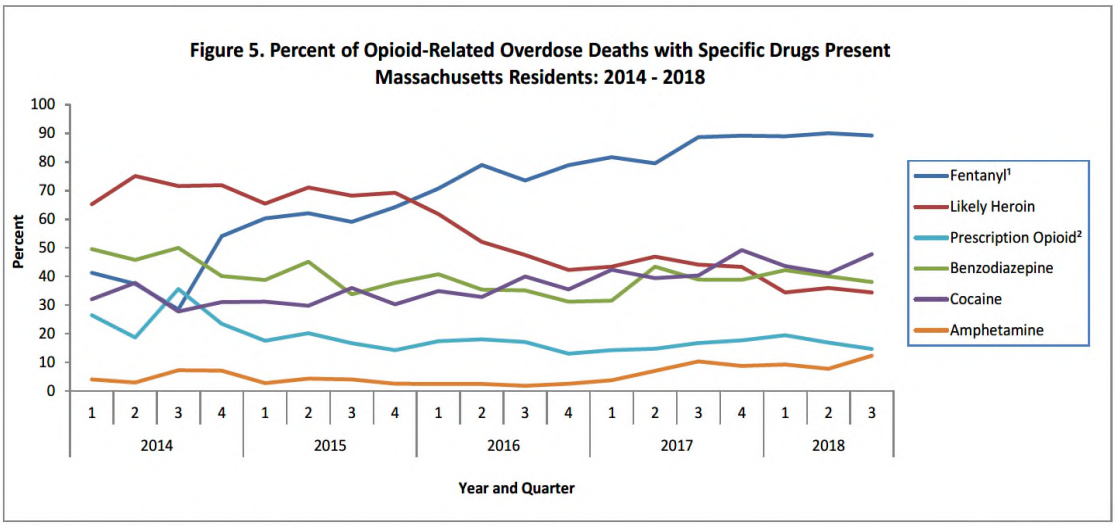
Purdue's OxyContin is just one of the abuse deterrent formulations available and currently accounts for less than 2% of the national opioid market. Ex. J at 9.

C. Outside Of This Case, The Commonwealth Acknowledges That The Opioid Abuse Crisis Is "A Complex Issue With A Number Of Contributing Factors"

In August 2015, the Commonwealth passed Chapter 55 of the Acts of 2015 "An Act Requiring Certain Reports For Opiate Overdoses" and ordered that "the secretary of health and human services, in collaboration with the department of public health shall conduct or provide for an examination of the prescribing and treatment history . . . of persons in the commonwealth who suffered fatal opiate overdoses in calendar year 2014 and shall make a report in an aggregate and de-identified form on trends discovered through the examination" Chapter 55 Section 1. According to the Commonwealth's dedicated Chapter 55 website, "This new law permits the analysis of different government datasets to guide policy decisions and to better understand the

opioid epidemic." Ex. F at 3. The Commonwealth recognizes in the home-page of the Chapter 55 website that "no single substance or health care practice is solely responsible for the current opioid crisis. Rather, it's a complex issue with a number of contributing factors." *Id.* at 2. Likewise, in the 2016 Chapter 55 report "An Assessment of Opioid Related Deaths (2013-2014)," the Commonwealth determined that heroin and fentanyl—not Purdue opioids—were the real drivers of opioid overdose deaths in Massachusetts.[8] In fact, the 2016 report noted that "illegal drugs appear more likely [than prescription medications] to be the direct cause of death" (Ex. D at 9), and the "proximal causes of overdose" (Ex. D at 27). According to the Commonwealth, approximately 83% of people who died from opioid-related overdose had illicit or likely illicit substances in their system at the time of death. Ex. D at 46. And the most recent data available from the Commonwealth shows that 89% of opioid related overdoses in 2018 had a positive screen result for fentanyl. Ex. G at 2. This graphic published by the Commonwealth just weeks ago demonstrates the increasing prevalence of fentanyl in opioid related deaths and the small percentage involving prescription opioids:

[8] *See* Ex. D at 16 ("[O]pioid-related deaths began increasing very sharply in 2012…. First, the number of opioids prescribed to residents of Massachusetts increased roughly 7% per year since 2000. There was, however, no sharp increase in prescribed opioids beginning in 2012. In contrast, recent toxicology data suggest that the increased presence of Fentanyl in post-mortem cases roughly matches the increase in opioid-related deaths …. Heroin and/or Fentanyl, and benzodiazepines are present at the majority of opioid overdose deaths and thus are likely to be driving the increases in overdose.") *Id.* at 27.



1. This is most likely illicitly produced and sold, **not** prescription fentanyl
2. Prescription opioids include: hydrocodone, hydromorphone, oxycodone, oxymorphone, and tramadol

Please note that previous estimates may change slightly as DPH routinely receives updated toxicology data from the Office of the Chief Medical Examiner and the Massachusetts State Police.

Moreover, the Commonwealth's own Department of Public Health determined over a decade ago, based on discussions with eight different treatment providers, that "practically everyone they saw in their treatment programs who was having a problem with OxyContin or another opioid, began their drug addiction by abusing alcohol and/or marijuana." *See* Ex. H at 14. And the Commonwealth has further acknowledged that its own failure to effectively combat illegal drug use and diversion through its Prescription Monitoring Program (PMP) have exacerbated the problem. *See* Ex. M at 22 (noting that the PMP program "lacked staffing and was ignored as fraudulent prescriptions and prescription overdose deaths rose at alarming rates" and that "[t]he lack of dedicated resources to the Commonwealth's PMP . . . cost the state hundreds of millions of dollars.").

Despite these conclusions by the Department of Health, the Attorney General's Amended Complaint does an about face and seeks to hold Purdue responsible for the opioid abuse crisis in Massachusetts. The Amended Complaint ignores this crucial context—that the opioid abuse crisis is a complex, multifactorial societal issue—and instead sets forth a misleading narrative in an

attempt to litigate this case in the court of public opinion. The number of inaccurate characterizations made by the Commonwealth regarding Purdue and its executives and directors are too numerous to set forth in full in this motion, but a few examples are illustrative of the broader strategy pursued by the Attorney General:

Reformulated OxyContin: The Amended Complaint states that the Purdue board of directors was in possession of an independent report criticizing Purdue's innovative abuse-deterrent formulation of OxyContin. *See, e.g.*, Am. Compl. ¶ 484. In fact, the report in question explicitly recognized that the abuse-deterrent formulation had averted ***thousands*** of cases of abuse. In April 2010, FDA approved a reformulated version of OxyContin developed by Purdue. Reformulated OxyContin is designed to deter abuse by adding a high molecular weight polymer, polyethylene oxide ("PEO"), which makes the tablet difficult to crush, and very thick when exposed to liquid, thereby deterring abuse. Purdue worked for years to develop the new formulation, investing hundreds of millions of dollars, and it was the first FDA-approved opioid with abuse deterrent properties. While the Commonwealth now criticizes reformulated OxyContin for not deterring all types of abuse, following FDA approval of reformulated OxyContin, the Massachusetts Attorney General explicitly commended FDA for supporting abuse-deterrent formulations and the Commonwealth made the decision to require its own employee health benefits program to cover these formulations, deeming them safer than preexisting alternatives.[9] Massachusetts' own Medicaid plan today includes "Oxycontin (oxycodone extended-release tablet)" as a "BP [Brand Preferred]" covered medication on the MassHealth Drug List. Ex. O at

[9] Chapter 258 of the Acts of 2014 "An Act To Increase Opportunities For Long-Term Substance Abuse Recovery."

3. Scientific studies also establish that Reformulated OxyContin reduces OxyContin abuse.[10] Accordingly, in 2013, three years after its launch, FDA reviewed the available scientific data and approved the addition of abuse-deterrent information in the OxyContin labeling—the first abuse-deterrent labeling for an opioid. The Commonwealth's assertion that Purdue did not believe reformulated OxyContin deterred abuse of OxyContin is contradicted by the document cited in the Amended Complaint, the Commonwealth's own prior actions and statements, and FDA.

Higher Doses: The Amended Complaint repeatedly asserts, without support, that Purdue inappropriately instructed its sales representatives to push doctors to prescribe more profitable higher doses of OxyContin. *See, e.g.*, Am. Compl. ¶¶ 709-713. In fact, Purdue has always sold OxyContin in a variety of doses that allow doctors to more easily titrate up and down to find the appropriate dose for pain relief in a particular patient. *See* OxyContin Labeling Ex. B at Section 2.5 ("Individually titrate OXYCONTIN to a dosage that provides adequate analgesia and minimizes adverse reactions. Continually reevaluate patients receiving OXYCONTIN to assess the maintenance of pain control, signs and symptoms of opioid withdrawal, and adverse reactions, as well as monitoring for the development of addiction, abuse and misuse . . ."). This is in line with accepted medical practice that a physician and patient individualize therapy to achieve pain

[10] *See, e.g.*, Hui G. Cheng & Paul M. Coplan, *Incidence of Nonmedical Use of OxyContin and Other Prescription Opioid Pain Relievers Before and After the Introduction of OxyContin with Abuse Deterrent Properties*, POSTGRAD MED. (2018); Institute for Clinical and Economic Review, *Abuse-Deterrent Formulations of Opioids: Effectiveness and Value, Final Evidence Report* (Aug. 8, 2017); Christopher M. Jones et al., *Trends in the Nonmedical Use of OxyContin, United States, 2006 to 2013*, CLIN. PAIN, Vol. 33, No. 5, 452-61 (May 2017); Stevan Geoffrey Severtson et al., *Sustained Reduction of Diversion and Abuse After Introduction of An Abuse-Deterrent Formulation of Extended Release OxyCodone*, DRUG ALCOHOL DEPEND., Vol 168, 219-29 (2016); PM Coplan et al., *The Effect of an Abuse-Deterrent Opioid Formulation (OxyContin) on Opioid Abuse-Related Outcomes in the Postmarketing Setting*, CLIN. PHARMACOL. THER., Vol. 100, No. 3, 275-86 (Sept. 2016); Theodore J. Cicero & Matthew S. Ellis, *Abuse-Deterrent Formulations and the Prescription Opioid Abuse Epidemic in the United States: Lessons Learned from OxyContin*, JAMA PSYCHIATRY, Vol. 72, No. 5, 424-29 (May 2015); Edward Michna et al., *Use of Prescription Opioids with Abuse-Deterrent Technology to Address Opioid Abuse*, CURR MED RES OPIN., Vol. 30, No. 8, 1589-1598 (2014).

relief through incremental dose escalation, as long as no serious risks emerge. Contrary to the Commonwealth's allegations, Purdue consistently issued warnings about the potential, well-known side effects of the highest OxyContin doses. Purdue specifically instructed that a patient should start with a low dose and that the highest doses were appropriate only for opioid tolerant patients. Indeed, OxyContin's FDA-approved labeling has always contained warnings about increasing dose levels. And the document the Commonwealth cites in support of this argument, an August 2013 visual aid available for use by Purdue's sales representatives, *see* Am. Compl. ¶ 713 n.858, (citing 2013-08-06 visual aid, PPLPC028000497109) ***repeatedly*** discloses (at least 6 times in the single document) that the higher doses carry potentially greater risks and that "OxyContin 60 mg and 80 mg tablets are for use in opioid-tolerant patients only." Thus, this document and others demonstrate that Purdue encouraged doctors to use the appropriate dose of their products to allow the patient to receive adequate pain relief.

Mischaracterization of Purdue's Support of Educational Initiatives: The Commonwealth alleges that "Purdue got to control research on the treatment of pain coming out of a prominent and respected institution of learning." Am. Compl. ¶ 280. This is a reference to educational programs provided by Purdue to Tufts Health Plan providers. In fact, the cited document does not demonstrate that Purdue "controlled research." Rather, Purdue presented a program called "The OxyContin Crisis" as part of a broad effort by Purdue to address prescription medication abuse awareness and prevention with a number of different organizations and healthcare providers. Among the hundreds of programs Purdue supported across the country are programs in Massachusetts entitled "Tufts Health Care Institute Program on Opioid Risk Management", "Safe and Effective Opioid Prescribing for Chronic Pain" and "Risk Evaluation and Mitigation Strategies and Opioid Drugs: What the Pharmacist Needs to Know." Purdue did

not control the content of any of these presentations. The Commonwealth ignores the fact that Purdue also provided large grants to the Massachusetts-based National Association of State Controlled Substance Authorities, and that Purdue gave grants unrelated to opioids to support Massachusetts-based charitable institutions.

Mischaracterizations About Individual Defendants: The Commonwealth also makes numerous allegations about certain individual defendants based on internal Purdue business documents that the Commonwealth grossly mischaracterizes and takes out of context. By one of many examples, the Amended Complaint portrays Dr. Richard Sackler as heartlessly responding to learning that "a federal prosecutor reported 59 deaths from OxyContin in a single state" by saying: "This is not too bad. It could have been far worse." Am. Compl. ¶ 182. But the e-mail is nothing more than an exchange in which Dr. Sackler forwards an email to others at Purdue consisting entirely of a New York Times article with the "subject" heading "NYTimes.com Article: Cancer Painkillers Are Being Abused." Within that lengthy article was a reference to 59 overdose deaths. As the context makes clear, far from callously viewing 59 deaths as "not too bad," Dr. Sackler was merely commenting about the nature of recent press coverage. As another example, the Amended Complaint claims that one director "asked staff what they were doing to fight back to convince doctors and patients to keep using the drug" against a report that "Purdue's reformulation of OxyContin was not a cost-effective way to prevent opioid abuse." Am. Compl. ¶ 484. The Commonwealth strategically omitted the fact that this report recognized that abuse deterrent opioids averted thousands of cases of abuse. *See* p. 14. Further, the director's response to an email discussing this report and a planned response to it was: "What was Purdue[']s involvement in 1-4 of the remedial action plan." The claim that this director urged "fighting back

to convince doctors and patients to keep using the drug" is a creation of the Commonwealth that appears nowhere in the cited document.

* * *

These are just a handful of the inaccuracies that appear throughout the Commonwealth's Amended Complaint. If the Commonwealth had ***facts*** to support its narrative, it would have included them in the Amended Complaint. It is telling that the Attorney General's office chose instead to resort to selective (and misleading) citation of Purdue's internal business documents to attract media focus. It also is significant that the public health officials tasked with solving the opioid abuse crisis in Massachusetts have reached conclusions at odds with the assertions of the Attorney General.

LEGAL STANDARD

To survive a motion to dismiss for failure to state a claim on which relief can be granted, Plaintiff's complaint must allege facts '"plausibly suggesting (not merely consistent with)' an entitlement to relief." *Iannacchino v. Ford Motor Co.*, 451 Mass. 623, 636 (2008) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)). Although a court must accept as true all of the factual allegations contained in a complaint, that doctrine does not apply to legal conclusions. *Schaer v. Brandeis Univ.*, 432 Mass. 474, 477 (2000). Threadbare recitals of the legal elements, supported by mere conclusory statements, do not suffice to state a cause of action. *Iannacchino*, 451 Mass. at 632. To avoid dismissal, the factual allegations underlying the complaint must go beyond "labels and conclusions" and "be enough to raise a right to relief above the speculative level." *Id.* at 636.

ARGUMENT

The Commonwealth asserts two causes of action against Purdue—a claim under Chapter 93A for allegedly "failing to disclose material risks to get more patients on its opioids at higher doses for longer time" (*see* Amended Complaint ¶ 895), and a common law claim for "creating and maintaining a public nuisance of addiction, illness and death that significantly interferes with the public health, safety, peace, comfort and convenience." (*see* Amended Complaint ¶ 904). For the reasons stated below, both of these claims must be dismissed.

I. STATEMENTS THAT COMPORT WITH FDA-APPROVED MATERIALS ARE NOT MISLEADING OR ACTIONABLE AS A MATTER OF LAW.

The Commonwealth contends that Purdue should be liable under Massachusetts law because it sold prescription opioids that supposedly are "extraordinarily dangerous," are "deadly," "put[] patients at risk," and are "no more effective or safer than intermittent use of immediate release opioids." Am. Compl. ¶¶ 16, 49, 104. In other words, the Commonwealth believes that Massachusetts law required Purdue either to stop selling opioids altogether, to sell only immediate release opioids, to sell opioids only for short-term treatment, or to sell only lower dose opioids. These claims directly conflict with FDA's decision to approve the sale of the opioids at issue in this litigation— OxyContin®, Butrans®, and Hysingla® —and FDA-approved labeling that accompanies those products. FDA's approval means it found "substantial evidence that the drug will have the effect it purports or is represented to have" and that these medications are ***safe and effective*** to treat chronic pain. 21 U.S.C. § 355(d); *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 239 (3d Cir. 2012) ("To obtain FDA approval, drug companies generally must submit evidence from clinical trials and other testing that evaluate the drug's risks and benefits and demonstrate that it is safe and effective for all of the indications prescribed, recommended, or suggested on the drug's label."). Indeed, the Commonwealth's

accusations of falsity and deception are an attack on FDA's expert conclusion that Purdue's opioids are safe and effective for the long-term treatment of chronic pain. Federal law prohibits exactly what the Commonwealth seeks to do here: to "second guess" FDA's well-informed determinations regarding the sale and labeling of prescription drugs. *See*, *e.g.*, *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34 (1st Cir. 2015); *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803 (7th Cir. 2018).

Moreover, the allegations in the Amended Complaint contradict the Commonwealth's own actions and statements with regard to prescription opioids. Its current contentions regarding prescription opioids are at odds with the findings of the Commonwealth's own task force on opioid issues, which has repeatedly reaffirmed the need to "ensure access to pain medication for individuals with chronic pain" (Ex. N at 2), noting that "prescription opioid pain medications serve an important and legitimate role in the treatment of pain" (Ex. P at 11). The allegations in the Amended Complaint are further belied by the Commonwealth's actions. If the Commonwealth truly believed its own allegations, it certainly would not continue to cover Purdue's opioid medications as a "brand preferred" medication in its state-funded healthcare programs. *See* Ex. O at 6.

A. Purdue's Marketing Was Consistent With FDA-Approved Language And Is Therefore Not Actionable.

The Commonwealth claims that it is not critiquing the relevant FDA-approved labeling of Purdue's opioids, but rather Purdue's marketing of those opioids. This is a distinction without a difference, because the marketing practices the Commonwealth claims were improper—including claims relating to OxyContin's appropriateness for long-term treatment of chronic pain, Am. Compl. ¶¶ 84-97, and maximum dosing, Am. Compl. ¶¶ 67-83—were consistent with FDA-approved product labeling. And doctors at all times have had access to FDA-approved label, which

is crystal clear about the risk of abuse and addiction. *See* Ex. B. Accordingly, the Commonwealth's claims necessarily "conflict[] with FDA's jurisdiction over drug labeling, and specifically its approval of" those indications. *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228, 1234 (S.D. Fla. 2007) (analyzing Massachusetts law); *cf. Zogenix, Inc. v. Patrick*, 2014 WL 1454696, at *2 (D. Mass. Apr. 15, 2014). Statements that "generally comport with [a medication's] approved label" are "not misleading as a matter of law." *Prohias*, 490 F. Supp. 2d at 1235 ("The information included in the labeling of a new drug reflects a determination by FDA that the information is not 'false or misleading' . . . . the alleged advertisements generally comport with the approved label and are therefore not misleading as a matter of law"); *see also Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998) (dismissing false advertising claims "as a matter of law" because challenged statements were "similar enough to the [FDA-] approved statements . . . that they [were] neither false nor misleading"). Where, as here, the representations and conduct that the Commonwealth claims were deceptive conform with determinations made by FDA in the exercise of its regulatory authority, *see supra*, those representations cannot be false, fraudulent, deceptive, or misleading. *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 2014 WL 866571, at *4 (D. Mass. Mar. 5, 2014), *aff'd on other grounds*, 779 F.3d 34 (1st Cir. 2015).

B. The 2007 Consent Judgment Estops The Commonwealth From Arguing That Purdue's Statements Are Misleading.

The 2007 Consent Judgment between the Commonwealth and Purdue is another bar to the state-law misrepresentation-based claims the Commonwealth asserts here. The Consent Judgment entered into between Purdue and the Commonwealth expressly recognizes the importance of OxyContin as a treatment for chronic pain and the critical role FDA serves to regulate opioid medications. Ex. A ¶ 3. Specifically, it directs that: "Purdue shall, consistent with the Package Insert, or as otherwise permitted by FDA, not promote or market OxyContin in a manner that:

(a) avoids or minimizes the fact that OxyContin is indicated for moderate to severe pain when a continuous around-the-clock analgesic is needed for an extended period of time." *Id.* Additionally, the Consent Judgment prohibits marketing OxyContin "in a manner that is, directly or indirectly, inconsistent with the 'Indication and Usage' section of the package insert for OxyContin." *Id.*

As a matter of law, the Commonwealth is estopped from arguing that marketing statements consistent with FDA-approved materials are misleading. The terms of the Consent Judgment ***require*** Purdue's promotions to comply with FDA labeling and indication—and FDA has approved Purdue opioids to treat chronic pain. The Commonwealth is seeking to hold Purdue liable for failing to provide warnings which FDA, the expert agency, declined to make regarding high dose, long duration opioid treatment. The Commonwealth cannot now argue that Purdue should have stopped selling or promoting opioid medications for long-term use. Rather, the Commonwealth is judicially estopped from advancing claims of misrepresentation based on statements that were permitted or required under the 2007 Consent Judgment. *See Otis v. Arbella Mut. Ins. Co.*, 443 Mass. 634, 639-640 (2005) ("Judicial estoppel is an equitable doctrine that precludes a party from asserting a position in one legal proceeding that is contrary to a position it had previously asserted in another proceeding."); *see generally Franco v. Selective Ins. Co*., 184 F.3d 4, 9 (1st Cir. 1999) ("Consent judgments may be given collateral estoppel effect if the parties clearly intend issues to be settled for the purposes of subsequent litigation between them.").

II. THE CHAPTER 93A CLAIM MUST BE DISMISSED BECAUSE THE CONDUCT ABOUT WHICH THE COMMONWEALTH COMPLAINS FALLS SQUARELY WITHIN THE PERMITTED PRACTICES EXEMPTION OF THAT STATUTE.

Since it was first enacted in 1967, Mass. Gen Laws ch. 93A has contained a very specific and important exemption. Section 3 of that statute states that:

> Nothing in this chapter shall apply to transactions or actions otherwise permitted under laws as administered by any regulatory board or officer acting under statutory authority of the commonwealth or of the United States.

This exemption is included in the statute precisely because the Massachusetts legislature fully understood that a plaintiff—here, the Attorney General—must not be allowed to substitute its judgment for the judgment of another regulatory body charged with overseeing the conduct at issue. While it is true that the defendant bears the burden of establishing that the exemption applies, the Supreme Judicial Court has fully recognized that the question of whether this exemption applies is appropriate for decision on a motion to dismiss. *Fleming v. Nat'l Union Fire Ins. Co.*, 445 Mass. 381, 389-391 (2005). In order for the exemption to apply, the defendant must show more than the mere existence of a related or even overlapping regulatory scheme that covers the transaction, but that the practice has been affirmatively authorized by the regulatory body. *See id*. An analysis of the facts alleged by the Commonwealth makes clear that this exemption applies here.

Although the Amended Complaint takes a "kitchen sink" approach to pleading, the allegations relating to the 93A claim can be summarized as follows: (1) that Purdue misled doctors in order to cause them to prescribe higher dosages to their patients, and (2) that Purdue "deceived [doctors into prescribing] its drugs for longer and more harmful periods of time." *See* Am. Compl. ¶¶ 2, 895. But the Commonwealth fails to recognize that FDA has considered these precise issues with respect to Purdue's labeling of its drugs, and affirmatively decided that the available science did not support imposing limits on dosages or duration of use. Indeed, as noted above, the July 2012 PROP Petition specifically requested FDA to add "a maximum daily dose" limitation for non-cancer pain and to add "a maximum duration of 90 days for continuous [daily] use" for non-cancer patients. Over a fourteen month period, FDA reviewed the Petition, evaluated the cited

studies, researched all of the available scientific literature, held public hearings and considered the opinions of experts, medical associations, patients, and almost 2000 public comments. Following this intensive review and analysis, FDA released its findings on September 10, 2013 and stated that "[t]he Agency declines to specify or recommend a maximum daily dose or duration of use for any opioid at this time." *See* Ex. C at 11. More specifically, FDA found that "the scientific literature does not support establishing a maximum recommended daily dose", and likewise that after a review of all of the relevant scientific data, "FDA has determined that limiting the duration of use for opioid therapy to 90 days is not supportable," and "[t]hus, the Agency denies this request." *See* Ex. C at 12, 14. Following these findings, FDA did not direct Purdue to revise its labeling or marketing of opioids with respect to maximum dosage or duration, and declined to add a warning that high doses or long durations of opioid treatment create greater risks to patients. *See id.* at 12-16.

With this context, it is clear that the Commonwealth is attempting to hold Purdue liable under G.L. c. 93A for precisely the conduct that FDA has already carefully reviewed and authorized. In these circumstances, numerous courts have recognized that the "permitted practices" exemption of G.L. c. 93A applies, and the claim must be dismissed. For example, in *Reckis v. Johnson & Johnson*, 471 Mass. 272 (2015), the plaintiffs alleged that their minor child developed Toxic Epidermal Necrolysis (TEN), a debilitating and near fatal condition causing respiratory failure, blindness and skin lesions, after using Children's Motrin and that Johnson & Johnson violated G.L. c. 93A by continuing to market the drug without warning of this risk. The Superior Court denied the 93A claim under the "permitted practices" exception because FDA had conducted a lengthy review and approval process and had approved the exact text of the label for the drug at issue. The Superior Court's decision was affirmed by the Supreme Judicial Court. *Id.*

at 282 n.20. *See also, Prohias*, 490 F. Supp. 2d at 1234 (holding that the "permitted practices" exemption barred plaintiff's 93A claim against a drug manufacturer where the advertising and marketing in question was generally consistent with claims FDA had approved); *O'Hara v. Diageo-Guiness, USA, Inc.*, 306 F. Supp. 3d 441 (D. Mass 2018) (finding a "permitted practice" and dismissing 93A claim regarding bottle and carton labeling because the contents had been specifically authorized by a federal agency); *Animal Legal Def. Fund Boston, Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278, 283-84 (D. Mass. 1986), *aff'd*, 802 F.2d 440 (1st Cir. 1986) (finding 93A does not apply as "[a]ntibiotic use in animals that complies with the federal scheme does not violate the Massachusetts consumer protection statute").

The foregoing makes clear that because FDA has specifically reviewed the precise conduct relating to limits on higher doses and long duration use that the Commonwealth relies on for its 93A claim, and because FDA has expressly found that the scientific evidence does not support such limits, Purdue's conduct falls directly within the "permitted practices" exemption, and the 93A claim must be dismissed.

III. THE COURT SHOULD DISMISS THE AMENDED COMPLAINT BECAUSE THE COMMONWEALTH DOES NOT ADEQUATELY PLEAD CAUSATION.

Causation is a required element of both of the Commonwealth's claims.[11] The Commonwealth must demonstrate both that Purdue was the cause in fact and the proximate cause of its injury. Cause in fact means the injury or harm would not have occurred but-for the

[11] Public nuisance claims require a showing of causation. *McKenna v. Andreassi*, 292 Mass. 213, 217 (1935) (public nuisance). While the focus of Chapter 93A is on "the defendant's conduct" rather than "individualized injury," *Commonwealth v. Ortho-McNeil-Janssen Pharm., Inc.*, No. CIV.A. 2011-2811-BLS, 2012 WL 5392617, at *3 (Mass. Super. Oct. 5, 2012), the Commonwealth must still demonstrate "'that the defendant's unfair or deceptive act caused an adverse consequence or loss,'" *Commonwealth v. Bragel*, No. CIV.A. 2012-865-C, 2013 WL 7855997, at *2 (Mass. Super. Dec. 3, 2013) (citing *Rhodes v. AIG Domestic Claims, Inc.*, 461 Mass. 486, 496 (2012) (dismissing c. 93A, § 4 claim where the Commonwealth alleged "entirely speculative" harm).

defendant's conduct. *Jorgensen v. Mass. Port Auth.*, 905 F.2d 515, 522-523 (1st Cir. 1990). Proximate cause exists where "based on considerations of policy and pragmatic judgment," the injury to the plaintiff "was a foreseeable result" of the defendant's actions. *Kent v. Commonwealth*, 437 Mass. 312, 320 (2002). With respect to proximate cause, "[i]f a series of events occur between the negligent conduct and the ultimate harm, the court must determine whether those intervening events have broken the chain of factual causation or, if not, have otherwise extinguished the element of proximate cause and become a superseding cause of the harm." *Id.* at 321. The Commonwealth does not adequately plead Purdue's alleged conduct was the but-for or proximate cause of the claimed harm. Because of these pleading defects, the Commonwealth's claims must be dismissed.

A. The Commonwealth Does Not Adequately Plead Purdue's Conduct Was The But-For Cause Of The Alleged Harm.

The Commonwealth faces an insurmountable pleading hurdle in this case. The medications manufactured by Purdue are available lawfully only with a valid prescription from a healthcare professional, who is known as the "learned intermediary." *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 80 (1st Cir. 1992) (applying Massachusetts law); *see also Cottam v. CVS Pharmacy*, 436 Mass. 316, 322, (2002). The Commonwealth therefore has to plead and prove facts showing that Purdue's statements caused individual prescribers to write prescriptions they otherwise would not have written, and that those prescriptions were improper or unnecessary. *See, e.g., Bodie v. Purdue Pharma Co.*, 236 F. App'x 511, 520-22 (11th Cir. 2017).

The Commonwealth fails to meet its pleading burden to show that Purdue's alleged misrepresentations were the but-for cause either of any particular prescription or of the Commonwealth's claimed injury. *See City of Chicago v. Purdue Pharma L.P.*, 2015 WL 2208423, at *14 (N.D. Ill. May 8, 2015) ("the [Plaintiff] does not allege[] the identities of doctors who, ***as a***

result of one or more of defendants' alleged misrepresentations, prescribed opioids for chronic pain.") (emphasis added); *see also In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 289 F. Supp. 3d 247, 257 (D. Mass. 2018) ("With respect to but-for causation, a plaintiff must produce evidence that he/she was injured by reason of a defendant's violation."). Nor does the Commonwealth make any allegations that the doctors identified in the Amended Complaint prescribed opioids manufactured by Purdue on the basis of any misrepresentation. *See Ferreira v. Sterling Jewelers, Inc.*, 130 F. Supp. 3d 471, 478-479 (D. Mass. 2015) ("the plaintiff must show a causal connection between the deception and the loss . . . . [and] is required to prove that the defendant's unfair or deceptive act caused an adverse consequence or loss.").

The Commonwealth's allegations in this case actually undermine any plausible causal link between its injuries and Purdue's actions. The Commonwealth alleges that a number of Massachusetts physicians such as Dr. Walter Jacobs, Am. Compl. ¶¶ 117-122, Dr. Conrad Benoit, Am. Compl. ¶¶ 128-133, Dr. Yoon Choi, Am. Compl. ¶ 134, Dr. Fernando Jayma, Am. Compl. ¶¶ 135-139, Dr. Ellen Malsky, Am. Compl. ¶¶ 140-143, and Dr. Fathalla Mashali, Am. Compl. ¶¶ 144-148, wrote unnecessary or improper opioid prescriptions. But it does not allege any misrepresentations by Purdue that caused the physicians to write these prescriptions. To the contrary, the Amended Complaint suggests the identified doctors were motivated by personal financial gain. *See, e.g.*, Am. Compl ¶¶ 120, 123, 127. The allegations against the remaining physicians and clinics are similar. *Id.* ¶¶ 112-148. The Commonwealth therefore not only fails to identify a single wrongful prescription caused by Purdue's alleged misrepresentations—it also makes the contradictory claim that physicians and clinics prescribed opioid medications for personal gain. The Court should dismiss both Counts because of this failure to plead but-for causation.

B. The Commonwealth Does Not Adequately Plead Purdue's Conduct Was The Proximate Cause Of The Alleged Harm.

The Commonwealth also fails adequately to plead that Purdue's conduct was the proximate cause of the alleged harm. Less than 2% of all U.S. opioid prescriptions are for products manufactured by Purdue, and the Amended Complaint concedes that the overwhelming majority of individuals in the Commonwealth who died from an opioid overdose never received an OxyContin®, Butrans®, or Hysingla® prescription. *Compare* Am. Compl. ¶ 15 with ¶ 22. The Commonwealth's current public stance is that "no single substance or health care practice is solely responsible for the current opioid crisis. Rather, it is a complex issue with a number of contributing factors." *See* Ex. G. Yet the Commonwealth seeks to hold Purdue liable for the entire opioid abuse crisis. Even lawful prescriptions depend on multiple intervening actors and events, including: (1) the prescribing physician's exercise of independent medical judgment when diagnosing and treating patients; (2) each patient's decision whether and how to use a prescribed medication; (3) patient's response to the medication; and (4) the decision by an insurer to reimburse the prescription. All of these independent intervening factors negate a finding of proximate causation. *Russo v. Baxter Healthcare Corp*., 140 F.3d 6, 12 (1st Cir. 1998); *see also Bank of Am. Corp. v. City of Miami, Fla.*, 137 S. Ct. 1296, 1306 (2017) (proximate cause "requires some direct relation between the injury asserted and the injurious conduct alleged."); *Holmes v. Sec. Inv'r Prot. Corp.*, 503 U.S. 258, 268 (1992) ("[H]arm flowing merely from the misfortunes visited upon a third person by the defendant's acts was generally said to stand at too remote a distance."). Indeed, a Connecticut court recently dismissed nearly identical claims brought against Purdue on the basis that such claims are so lacking in proximate cause that to permit them to go forward "would risk letting everyone sue almost everyone else about pretty much everything that harms us." *City of New Haven v. Purdue Pharma, L.P.*, No. X07-HHD-CV 17 6086134-S, 2019

WL 423990, at *2 (Conn. Super. Ct. Jan. 8, 2019). The *New Haven* court found that any alleged injury by the plaintiffs is too "indirect" because there are at least nine links[12] in the alleged causal chain separating the conduct of manufacturers from any harm to the plaintiffs and those "links [are] too attenuated to support a claim." *Id.* at *4. For this reason, the court determined "allowing these kinds of lawsuits would lead to a wildly complex and ultimately bogus system that pretends to measure the indirect cause of harm to each individual and fakes that it can mete out proportional money awards for it. In short, our courts have declined to get out of the business of reasoned judgment and into the business of irrational speculation." *Id.* at *2.

This case presents similar proximate causation issues. For example, the physician, who as a "learned intermediary" exercises her or his medical judgment to decide whether or not to prescribe, severs any link between Purdue's conduct and any purported harm to the Commonwealth. *See Cottam*, 436 Mass. at 322; *see also MacDonald v. Ortho Pharm. Corp*., 394 Mass. 131, 136-137 (1985). Massachusetts courts have reasoned that "the physician's conduct acts as an intervening-superseding cause of the plaintiff's injury which vitiates any liability on the

[12] The nine links in the chain identified by the Connecticut court are:

> Link 1: The manufacturers make the opioids.
>
> Link 2: The manufacturers sell the opioids to the distributors.
>
> Link 3: The distributors sell the opioids to a pharmacy.
>
> Link 4: Doctors prescribe the opioids.
>
> Link 5: Patients take them.
>
> Link 6: Some patients become addicted.
>
> Link 7: The city must give emergency and social services to some addicts while the city's quality of life, property values and crime rate worsen from the spread of addiction, further straining city resources . . . .
>
> Link 8: Pills get loose and are sold on the black market creating other costly addicts.
>
> Link 9: Pills get too expensive or scarce for some addicts who turn to more accessible stocks of street fentanyl or heroin, creating costly addicts.

part of the manufacturer." *Garside*, 976 F.2d at 80. A complaint should be dismissed where, as here, an intervening cause breaks the chain of legal causation. *Kent*, 437 Mass. at 322. Given the critical role of the physician, courts routinely dismiss complaints when the plaintiff's allegations, like those here, would require an unworkable "inquiry into the specifics of each doctor-patient relationship implicated by the lawsuit" to demonstrate causation. *Ironworkers Local Union No. 68 v. AstraZeneca Pharm. LP*, 585 F. Supp. 2d 1339, 1344-45 (M.D. Fla. 2008); *see also Travelers Indem. Co. v. Cephalon, Inc.*, 620 F. App'x 82, 87 (3d Cir. 2015); *United Food & Commercial Workers Cent. Pa. & Reg'l Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255, 257 (9th Cir. 2010); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, 2010 WL 3119499, at *7-9 (S.D. Ill. Aug. 5, 2010); *In re Zyprexa Prods. Liab. Litig. (Hood v. Eli Lilly & Co.)*, 671 F. Supp. 2d 397, 453 (E.D.N.Y. 2009).

The Commonwealth's claims also seek to redress many illegal acts, including the use of opioids that were unlawfully obtained and the abuse of illegal street drugs such as illicit fentanyl and heroin. Under this theory of causation the Commonwealth seeks to hold Purdue liable for a whole host of alleged injuries far removed from a physician prescribing a Purdue medication. Those alleged harms happen because of numerous additional intervening acts, including criminal acts by third parties such as drug dealers who sold deadly heroin and fentanyl in the Commonwealth. These are not Purdue's acts and any connection between Purdue and these illegal acts is too remote to be actionable. "[P]roximate cause 'generally bars suits for alleged harm that is 'too remote' from the defendant's unlawful conduct.'" *Bank of Am.*, 137 S. Ct. at 1306 (quoting *Lexmark Int'l Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 133 (2014)). Here, even the Commonwealth has acknowledged that illicit drugs are the primary driver of current opioid issues. It concluded in its first Chapter 55 report that "illegal drugs appear more likely to be the direct

cause of death" and the "proximal causes of overdose." One of the "Key Findings" of that report was that "Heroin and/or Fentanyl, and benzodiazepines are present in the majority of opioid overdose deaths and ***thus are likely to be driving the increases in overdose***." Ex. D at 9, 27 (emphasis added). The role of illicit fentanyl was further explained in the 2017 Chapter 55 Report "When illicit fentanyl became common in the drug supply in Massachusetts, the death rates went up sharply . . . ***evidence is emerging that fentanyl is a strong contributor to the sharp increase in opioid-related deaths in Massachusetts***." Ex. E at 32 (emphasis added). The Commonwealth's most recent opioid death statistics show that fentanyl was present in 89% of 2018 opioid death cases. Ex. G at 2. Thus, even under its own findings, the Commonwealth's causal theory simply is too attenuated.

IV. THE PUBLIC NUISANCE CLAIM FAILS.

Through its sweeping public nuisance claim, the Commonwealth seeks to hold Purdue solely liable for the entire opioid epidemic in the Commonwealth, including all costs associated with "opioid addiction, overdose, and death," "health care costs for individuals, children, families, and employers," "loss of productivity" and costs "to provide for the public health, safety, and welfare." Am. Compl. ¶ 267. In other words, the Commonwealth ignores the multiple sources of opioids sold in Massachusetts during the relevant time period, Am. Compl. ¶ 15, the outsized role of illegal street drugs in the current crisis, Am. Compl. ¶ 88, the Commonwealth's own admissions about doctors who over-prescribed opioids for their own financial gain, Am. Compl. ¶¶ 120, 123, 127 and the Commonwealth's own failures to effectively combat illegal drug use and diversion through its PMP. Instead, the Commonwealth contends that Purdue alone should be held responsible for all "addiction, illness, and death" related to any opioid use in Massachusetts. Am. Compl. ¶¶ 904-906. Such a claim must fail for multiple reasons.

First, the Commonwealth's public nuisance claim must be dismissed because it does not allege any interference with a public right. At most, the Commonwealth alleges a nuisance to some individuals and subsequent costs to the Commonwealth. *See, e.g.*, Am. Compl. ¶¶ 15, 22, 23, 26, 906.[13] But a public right is "more than an aggregate of private rights by a large number of injured people." *State v. Lead Indus., Ass'n*, 951 A.2d 428, 448 (R.I. 2008). Historically, Massachusetts nuisance law applied only to navigable roads and waterways and to the misuse of real property. *Jupin v. Kask*, 447 Mass. 141, 158 (2006) (affirming dismissal of public nuisance claim based on possession of a firearm citing as "traditional public nuisance cases" as those "involving highways and navigable streams" or "the keeping of diseased animals or the maintenance of a pond breeding malarial mosquitos."). The Commonwealth's public nuisance claim falls far outside this traditional scope of public nuisance law. *See also Town of Westport v. Monsanto Co.*, 2015 WL 1321466 at *2-3 (D. Mass. Mar. 24, 2015).

The court's reasoning in *Jupin* is in line with decisions from courts across the country that have refused to "allow[] a public nuisance claim to proceed against manufacturers for lawful products that are lawfully placed in the stream of commerce." *Camden Cty. Bd. of Chosen Freeholders v. Beretta, U.S.A. Corp.*, 273 F.3d 536, 540 (3d Cir. 2001); *see also Ashley Cty., Ark. v. Pfizer, Inc.*, 552 F.3d 659, 673 (8th Cir. 2009); *City of Perry, Iowa v. Procter & Gamble Co.*,

[13] To the extent the Commonwealth relies on harm to individual citizens to establish its public nuisance claim, the derivative injury rule bars those claims. Proximate cause requires "direct relation between the injury asserted and the injurious conduct alleged. Thus, a plaintiff who complained of harm flowing merely from the misfortunes visited upon a third person by the defendant's acts was generally said to stand at too remote a distance to recover." *Holmes v. Secs. Inv. Protection Corp.*, 503 U.S. 258, 268-269 (1992). Accordingly, Massachusetts law does not recognize a claim for derivative injury. *Massachusetts Laborers' Health & Welfare Fund v. Philip Morris, Inc.*, 62 F. Supp. 2d 236, 246 (D. Mass. 1999). Courts across the country have applied the derivative injury bar to dismiss similar public nuisance claims to the one presented by the Commonwealth. *See, e.g., Ass'n of Wash. Pub. Hosp. Dists. v. Philip Morris, Inc.*, 241 F.3d 696, 707 (9th Cir. 2001); *Cty. of Cook v. Philip Morris, Inc.*, 817 N.E.2d 1039, 1044-46 (Ill. App. Ct. 2004); *People v. Sturm, Ruger & Co., Inc.*, 761 N.Y.S.2d 192, 194-99 (N.Y. App. Div. 2003); *Ganim v. Smith & Wesson Corp.*, 780 A.2d 98, 119-31 (Conn. 2001).

188 F. Supp. 3d 276, 291 (S.D.N.Y. 2016); *City of Phila. v. Beretta U.S.A. Corp.*, 126 F. Supp. 2d 882, 910 (E.D. Pa. 2000), *aff'd*, 277 F.3d 415 (3d Cir. 2002); *Town of Hooksett Sch. Dist. v. W.R. Grace & Co.*, 617 F. Supp. 126, 133 (D.N.H. 1984); *People ex rel. Spitzer v. Sturm, Ruger & Co.*, 761 N.Y.S.2d 192, 194-99 (N.Y. App. Div. 2003); *Ganim v. Smith & Wesson Corp.*, 780 A.2d 98, 119-31 (Conn. 2001), *State v. Lead Indus. Ass'n*, 951 A.2d 428 (R.I. 2008).

Recently, courts in Delaware and Connecticut dismissed nearly identical public nuisance claims against manufacturers of opioids. *See State of Delaware ex rel. Jennings v. Purdue Pharma L.P.*, No. N18C-01-223, 2019 WL 446382 (Del. Super. Ct. Feb. 4, 2019) (granting motion to dismiss nuisance claim brought by Delaware Attorney General); *City of New Haven*, 2019 WL 423990. For example, the Delaware court, noting "a clear national trend to limit public nuisance to land use" dismissed an opioid-based public nuisance claim brought by the Attorney General in that state, refusing to recognize a public nuisance claim for products. *See Delaware v. Purdue Pharma, L.P., et. al.*, at *12-13 *see also Grewal v. Purdue Pharma L.P.*, No. ESX-C-245-17, 2018 WL 4829660, at *17 (N.J. Super. Oct. 2, 2018) (dismissing public nuisance claim against opioid manufacturer "because the claim falls within the definition of a product liability action").

The Commonwealth's public nuisance claim is exactly the sort of poorly disguised, repackaged products liability claim courts have rejected. To allow public nuisance claims to proceed under these circumstances would "likely open the courthouse doors to a flood of limitless, similar theories of public nuisance, not only against these defendants, but also against a wide and varied array of other commercial and manufacturing enterprises and activities." *People ex rel. Spitzer v. Sturm, Ruger & Co.*, 309 A.D.2d 91, 93, 96 (N.Y. App. Div. 2003). Such a system would turn public nuisance into "a monster that would devour in one gulp the entire law of tort." *Tioga Pub. Sch. Dist. No. 15 v. U.S. Gypsum Co.*, 984 F.2d 915, 921 (8th Cir. 1993).

V. THE COMMONWEALTH SEEKS RELIEF TO WHICH IT IS NOT ENTITLED.

The Commonwealth seeks damages that are unavailable under its present claims. Among other things, the Commonwealth has requested the following relief:

- Disgorgement of "all payments received as a result of [Defendants] unlawful conduct";
- "Full and complete restitution to every person who has suffered any ascertainable loss by reason of [Defendants'] unlawful conduct";
- "Civil penalties of up to $5,000 for each and every violation of G.L. c. 93A, § 2";
- Attorney's fees as provided under G.L. c. 93A, § 4
- Reimbursement for "the cost of the Commonwealth's abatement efforts" and "compensatory damages for harms caused by the nuisance"

Am. Compl. "Prayer for Relief" at 273. However, public nuisance claims in Massachusetts are equitable in nature, so the only remedy available—should the claim be allowed to proceed—is abatement. *See Stop & Shop Companies, Inc. v. Fisher*, 387 Mass. 889, 894 (1983). The Court should thus strike the Commonwealth's request for any public nuisance damages that go beyond the equitable abatement remedy. Likewise, the statutorily-provided remedy for a 93A claim brought by the Attorney General is a civil penalty. As neither of the Commonwealth's claims support its request for disgorgement or restitution, these requests should be stricken.

Moreover, setting aside the question of whether the Commonwealth has standing to bring any such claim, Massachusetts courts have already determined that a defendant's legal responsibility "must be determined one participant at a time," and that attempts to subject a Defendant to "liability-in-gross" must be rejected. *Mass. Laborers' Health & Welfare Fund v. Philip Morris, Inc.*, 62 F. Supp. 2d 236, 246 (D. Mass. 1999). Therefore, at the very least, the Court should strike the Commonwealth's request for "restitution to every person who has suffered any ascertainable loss." Am. Compl. at 273.

VI. THE COMMONWEALTH'S CLAIMS ARE, IN PART, BARRED BY STATUTES OF LIMITATIONS.

Each of the Commonwealth's claims are barred, in part, by the applicable statutes of limitations. *O'Connell v. I.R.S.*, 2004 WL 1006485 at *4 (D. Mass. 2004) ("Compliance with the statute of limitations is a jurisdictional requirement to maintain suit."). In Massachusetts, the Commonwealth is subject to the same statutes of limitations as all other parties. *See* Mass. Gen. Laws Ann. ch. 260, § 18. The relevant statutes of limitations for the Commonwealth's claims are four years for the 93A claim and three years for both the public nuisance claims. *See* Mass. Gen. Laws Ann. ch. 260, § 5A (93A claim); *Taygeta Corp. v. Varian Assocs., Inc*., 436 Mass. 217, 220-21 (2002) (public nuisance claim).

Given the Tolling Agreement between the Commonwealth and Purdue, *see* Am. Compl. ¶ 839, the Commonwealth's claims would only be valid to the extent they are predicated on injuries occurring on/after August 3, 2012—in the case of the 93A claim—and on/after August 3, 2013—in the case of the public nuisance claim. Thus, the Court should dismiss any of the Commonwealth's claims to the extent they are based on actions that predate the applicable limitations periods. *See, e.g.*, Am. Compl. ¶¶ 13 ("[t]his suit addresses Purdue's misconduct since that 2007 Judgment."); 21 (citing statistics since May 2007); 22 (citing a 2009 investigation); 31-32 (citing Purdue's promotional activities "since 2007"); 39 (citing a 2008 publication); 42-43 (citing publications published in 2009); 44 (citing a 2007 publication); 55 (citing a 2009 publication); 56 (citing a 2011 advertisement); 60 (citing a sales script from 2011).

The discovery rule cannot salvage the Commonwealth's time-barred claims. Under the discovery rule "an applicable statute of limitations will not commence to run against the plaintiff until the plaintiff knows, or reasonably should have known, that he has been harmed and that such harm may be a product of someone's negligence." *Hanley v. Citizens Bank of Mass.*, 2004 WL

316143, at *2 (Mass. App. Ct. 2004). The Commonwealth's own initial Complaint made clear that the facts underlying the claims have long been known to the Commonwealth. The initial Complaint quoted from the text of articles detailing Purdue's supposed misconduct that were published in 2009, 2010, 2011 and 2013, and a 2012 letter from two U.S. Senators to Purdue describing their concerns about Purdue's marketing practices. *See* Compl. ¶¶ 162-170. Many documents cited in the Amended Complaint are also publicly available.[14] Moreover, to the extent any of these documents (or any other information) raised concerns for the Attorney General, she had authority under the Consent Judgment to request documents from Purdue. Thus, nothing was concealed from the Attorney General that would justify invocation of the discovery rule.

[14] *See, e.g.*, "In the Face of Pain Website" (cited in Am. Compl. ¶ 31), available at http://www.inthefaceofpain.com/, archived version available at https://web.archive.org/web/20130801000000*/http://www.inthefaceofpain.com/; "Resource Guide for People with Pain" (cited in Am. Compl. ¶ 32), available at thblack.com/links/rsd/ITFOPResourceGuide.pdf; "Exit Wounds (cited in Am. Compl. ¶ 32), a publicly available book (https://www.amazon.com/Survival-Management-Returning-Veterans-Families/dp/B002NRP2YC); Opioid Prescribing: Clinical Tools and Risk Management Strategies (cited in Am. Compl. ¶ 34), available at www.cecity.com/aapm/2009/opioids/opioids_print.pdf; Responsible Opioid Prescribing (cited in Complaint ¶ 35), a publicly available book (https://www.amazon.com/Responsible-Opioid-Prescribing-physicians-Guide/dp/B001392YFG/ref=sr_1_fkmr0_1?ie=UTF8&qid=1535734139&sr=8-1-fkmr0&keywords=responsible+opioid+prescribing+2007).

CONCLUSION

For the foregoing reasons, Purdue respectfully requests that the Court dismiss the Commonwealth's claims in their entirety.

Dated: March 1, 2019 Respectfully submitted,

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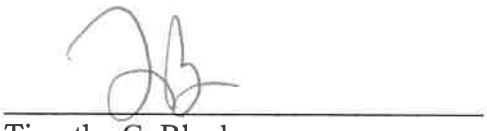

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CERTIFICATE OF RULE 9C CONFERENCE

I hereby certify that, I, Timothy C. Blank, counsel for Purdue Pharma L.P and Purdue Pharma Inc., conferred via phone with Gillian Feiner, counsel for the Commonwealth of Massachusetts, on February 25, 2019 at 11:40 am, in advance of serving Purdue's Motion to Dismiss the Commonwealth's First Amended Complaint, in a good faith effort to narrow areas of disagreement related to the subject of the motion to dismiss.

Signed this 1st day of March 2019.

Timothy C. Blank